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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,653	12/04/2000	Biaoyang Lin	P-IS 4367	3087

23601 7590 11/17/2003

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/17/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,653

Applicant(s)

LIN, BIAOYANG

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) 21-23, 5 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **08/27/03** has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 26-29 are examined in the instant application.

Claims 26-27 seem to be free of prior art and are allowable.

The following are the remaining rejections:

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claims 28-29 remain rejected under 35 USC 112, first paragraph pertaining to lack of clear written description of variants of SEQ ID No:2 for reasons already of record in paper No:19.

Applicant argues that the specification discloses sequences that can be common to the PAMP polypeptides. Applicant argues that in particular, a PAMP polypeptide having 90% or 95% identity with 350 residues of SEQ ID NO:2, including residues 1075 to 1382 of SEQ ID NO:2 contains only 1 out of 10 or 20 amino acids, respectively, different from the specified amino acids of SEQ ID NO:2. Applicant asserts that given

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the written description of SEQ ID NO:2 in figure 1 and further disclosure in the specification, Applicant was in possession of the claimed invention.

Applicant's arguments in paper No: 22 have been considered but are found not to be persuasive for the following reasons:

Contrary to Applicant's assertion, there is no disclosure of common structural attributes that identify the variants, nor there is disclosure of common function attributes that correlate with structure, because the function of a protein can be abolished, even with substitution of one amino acid, as taught by Burgess et al. There is no disclosure of which positions of the claimed 1 out of 10 or 20 amino acid that are substituted or deleted or added amino acids are within SEQ ID NO:2, such that common structural attributes could be determined and are correlated with function.

For reasons set forth above and in previous Office action, Applicant was not in possession of polypeptides that are at least 90% or 95% identical to 350 residues comprising residues 1075 to 1382 of SEQ ID NO:2.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claims 28-29 remain rejected under 35 USC 112, first paragraph pertaining to lack of enablement for variants of SEQ ID No:2 for reasons already of record in paper No:19.

Applicant argues that the specification provides guidance for making the claimed polypeptides, for example by teaching how many amino acids of SEQ ID NO:2 can be

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substituted, in particular, at most 10% or 5% of a stretch of 350 residues of SEQ ID NO:2.

Applicant asserts that the specification discloses that a variety of amino acid substitutions, in addition to conservative substitution, for example, naturally occurring variants of human PAMP of SEQ ID NO:2, such as species homolog, including a mammalian homolog, such as murine, bovine, or primate homolog or a non-mammalian homolog. Applicant asserts that said naturally occurring variants would retain a PAMP polypeptide function.

Applicant asserts that the specification discloses which amino acids that can be substituted, deleted or inserted, by teaching that a PAMP polypeptide having at least 90% or 95% amino acid identity with at least 350 residues of SEQ ID NO:2 can be species homolog.

Applicant further argues that it is routine methods to prepare a species homolog of SEQ ID NO:2 or another polypeptide having at least 90% or 95% amino acid identity with at least 350 residues of SEQ ID NO:2.

Applicant's arguments in paper No: 22 have been considered but are found not to be persuasive for the following reasons:

Although the specification discloses how many amino acids that can be substituted, deleted or added, the specification does not disclose which amino acids in which positions within the 350 amino acids of SEQ ID NO:2 that can be substituted, deleted or added.

Contrary to Applicant assertion, by disclosing that a PAMP polypeptide having at least 90% or 95% amino acid identity with at least 350 residues of SEQ ID NO:2 can be species homolog, the specification does not disclose which amino acids in which positions within or outside the 350 amino acids of SEQ ID NO:2 that can be substituted, deleted or added, for the following reasons: The specification does not disclose the structure of naturally occurring variants or species homolog, nor which amino acid positions of the naturally occurring variants or species homolog have been replaced or substituted or added by nature, such that the variants still have the function of PAMP polypeptide. Protein chemistry however is probably one of the most unpredictable areas of biotechnology, and even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristics of a protein, as taught by Burgess et al, Lazar et al, Tao et al, Gillies et al, all of record.

For the reasons set forth above and in previous Office action, it would be undue experimentation for one of skill in the art to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone

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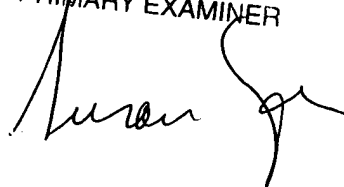
number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

November 10, 2003

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan Ungar', is written over the printed name and title.